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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/612,121	07/02/2003	Jamie L. Brewer	260385.20005	6561

7590 12/13/2006  
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EXAMINER

JUEDES, AMY E

ART UNIT PAPER NUMBER

1644

DATE MAILED: 12/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/612,121

Applicant(s)

BREWER ET AL.

Examiner

Amy E. Juedes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 17 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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### DETAILED ACTION

1. Applicant's remarks, filed 10/10/06, are acknowledged.
2. Claims 1-14 and 17-18 stand withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 15-16 are being acted upon.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Spinella et al., 1994, in view of Wei et al., 1994 and US patent 6,017,699 (of record).

As set forth previously, Spinella et al. teach that analysis of TCR gene expression, particularly by PCR, is becoming increasingly important to a variety of clinical programs (see pg. 111 in particular). Spinella et al. further teach employing a standard reference template in the PCR that consists of cloned TCR genes of the 24 known TCR V $\beta$  families (i.e. V $\beta$  1-24, see pg. 114 and Fig. 9.3, in particular). Spinella et al. further teach that including the reference templates is extremely important since it helps to ensure the accuracy of the analysis (see pg. 115, in particular). Furthermore, said reference template comprising the cloned genes of V $\beta$ 1-V $\beta$ 24 would comprise SEQ ID NO: 33-54, since these represent DNA fragments derived from V $\beta$ 1-V $\beta$ 24 TCR V regions.

Spinella et al. do not teach the TCRV $\beta$ 25 gene, or a kit comprising the reference templates, an enzyme, buffer solutions, and deoxynucleotide triphosphates.

Wei et al. teach the identification of a new TCRV $\beta$  gene segment, V $\beta$ 25 (see Fig. 1 in particular).

The '699 patent teaches that reagents necessary for performing an assay can be packaged in a kit as a matter of convenience (see column 6 in particular). The '699 patent also teaches that kits can comprise quantification reagents, including PCR reagents such as buffers, enzymes, and nucleoside triphosphates (see column 7 in particular).

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add the gene encoding the TCR V $\beta$ 25 region, as taught by Wei et al., to the standard reference template set comprising the TCR V $\beta$ 1-24 genes taught by Spinella et al. The ordinary artisan at the time the

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invention was made would have been motivated to do so, since Spinella et al. teach that a reference template comprising the V $\beta$  genes of all the known V $\beta$  families is extremely important since it helps to ensure the accuracy of TCR analysis, and Wei et al. teach that V $\beta$ 25 is a newly identified TCR V $\beta$  gene. Furthermore, the ordinary artisan would have been motivated to package the reagents necessary for performing the PCR reaction (an enzyme, buffers, and deoxynucleotide triphosphates), as taught by the '699 patent, along with the reference template made obvious by Spinella et al. and Wei et al. The ordinary artisan at the time the invention was made would have been motivated to do so since the '699 patent teaches that reagents necessary for performing an assay can be packaged in a kit as a matter of convenience. Furthermore, said reference template comprising the cloned genes of V $\beta$ 1-V $\beta$ 25 would comprise SEQ ID NO: 33-55, since these represent DNA fragments derived from V $\beta$ 1-V $\beta$ 25 TCR V regions.

Applicants arguments filed 10/10/06 have been fully considered, but they are not persuasive.

Applicant argues that the disclosure by Spinella of the cloned TCR genes corresponding to each of the 24 known TCR V $\beta$  families is too general and does not specifically disclose SEQ ID Nos: 35-55.

However, the instant claims are drawn to a kit "comprising" SEQ ID Nos: 33-55. SEQ ID Nos: 33-54 are primers derived from the sequences of V $\beta$ 1-V $\beta$ 24. Therefore, the entire cloned gene of said V $\beta$ 1-V $\beta$ 24 would "comprise" SEQ ID Nos: 33-54. Applicant has not provided any evidence that the cloned V $\beta$ 1-V $\beta$ 24 genes taught by Spinella et al. would not comprise SEQ ID Nos: 33-54.

Applicant further argues that the TCR V $\beta$ 25 gene taught by Wei et al. is over 960 nucleotides long, and is not the same as the instant nucleic acids which are at most 25 nucleotides long.

However, the instant claims are drawn to a kit "comprising" SEQ ID Nos 33-55. The nucleic acid sequence taught by Wei et al. comprises SEQ ID NO: 55 (see residues 589-611 in Fig. 1 of Wei et al.).

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E. Juedes, Ph.D. whose telephone number is 571-272-4471. The examiner can normally be reached on 8am - 5pm, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Amy E. Juedes, Ph.D.  
Patent Examiner  
Technology Center 1600  
November 14, 2006

  
11/19/06  
**G.R. EWOLDT, PH.D.**  
**PRIMARY EXAMINER**